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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* #1** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE REFERENCE TO FDA 510(k) CLEARANCE AND LACK OF FDA ENFORCEMENT

A. FDA 510(k) Clearance Regulations Are Not Safety Regulations

Bard's opposition rehashes many of its preemption arguments, putting forth the same unsuccessful argument that the post-*Lohr* medical devices have been reviewed for safety and efficacy. But as this court has already held, regulations governing the 510(k) clearance process are not safety standards as the clearance process does not independently establish the safety of medical devices. Rather, the process renders a comparative determination. (Doc. 8872, at 12-13).

Georgia Suggested Pattern Jury Instruction 62.670 states as follows:

> 62.670 Strict Liability; Design Defect; Compliance with Industry Standards or Government Regulations
>
> In determining whether a product was defective, you may consider proof of a manufacturer's compliance with ***federal or state safety standards or regulations*** and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

(Exhibit A, *Georgia Suggested Pattern Jury Instructions*, January 17, 2017 (5th Ed.) (emphasis added).) This pattern jury instruction limits the jury's consideration to only those standards and regulations related to "safety," which would exclude anything to do with 510(k) clearance. Moreover, these pattern jury instructions are born of and have evolved from the same cases[1] on which Defendants rely in claiming the federal standards a jury may consider are not limited to "safety" standards. Def. Resp. Mot., at 4.

Bard also admits that it does not intend to simply introduce evidence of its alleged compliance with applicable law and regulations. Rather Bard intends to argue that the FDA 510(k) process determined its IVC filters were safe and effective. Def. Resp. Mot., at 6.

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[1] The *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671 (Ga. 1994), case does not provide the broad scope Bard suggests but rather states that compliance with federal regulations does not conclusively eliminate liability. *Id.* at 675. *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997), similarly states that compliance with a federal regulation is a factor to determine if a manufacturer was reasonable in selecting a design. Yet the 510(k) clearance regulations do not require a product to take a particular form or adhere to particular specifications. *Riegel v. Medtronic*, 552 U.S. 312, 323 (2008).

This argument is wrong. To make matters worse and add confusion, Bard intends to rely on hearsay communications with the FDA to argue that compliance with 510(k) standards is steeped in safety review. The hearsay problem is exemplified by Plaintiff's inability to cross examine at trial (or even depose or informally interview) FDA witnesses regarding their internal documents and communications with Bard. Notably, the *Cisson* case applied Georgia law and recognized evidentiary issues that led to the exclusion of 510(k) clearance evidence. *See Cisson v. C.R. Bard, Inc*. 86 F. Supp. 3d 510 (S.D. W. Va. 2015), *aff'd sub nom*, 810 F.3d 913 (4th Cir. 2016).

Likewise, Bard's alleged compliance with 510(k) is not relevant to respond to or rebut a claim for punitive damages under Georgia law. Georgia's Annotated Code provides that punitive damages are available when the defendant's actions exhibit "willful misconduct, malice, fraud, wantonness, or oppression." Ga.Code Ann. § 51-12-5.1(b) (2014). "Such conduct is not mitigated by compliance with 510(k), a regulation 'intended merely to give manufactures the freedom to compete.'" *Cisson*, 86 F. Supp. 3d at 516 (quoting *Lohr*, 518 U.S. at 492)

Bard also indicates it will seek to introduce evidence of communications with the FDA concerning the EVEREST retrievability study conducted under the investigational device exception (IDE) code section of the FDA regulations. In addition to being more hearsay, this evidence is irrelevant and not probative of material facts or issues in this trial. Fed. R. Evid. 401. This Court has already recognized that under 21 C.F.R. § 807.87(*l*) the FDA can request additional information during the 510(k) process to determine substantial equivalence without implicating any type of safety determination. (Doc. 8872, at 12.) Even documents submitted by Bard to support its unsuccessful preemption motion clearly state IDE distribution and use of its devices is a means of collecting more data to determine substantial equivalence, not to support an independent determination of safety or effectiveness. (Doc. 5396, Exhibit A: "Declaration of Robert Carr In Support Of Defendants' Motion for Summary Judgment Regarding Preemption," Exhibit. 7, Sec. 17,

para 4)[2] This misplaced argument actually undermines Bard's claim that the FDA required Bard to conduct the EVEREST study since IDEs are not only voluntary applications, but also optional to manufacturers just like making a 510(k) application. Such additional information provided by a manufacturer to the FDA while seeking 510(k) clearance does not establish safety standards. In the end, there is no "clinical study" requirement under the 510(k) process because the FDA does not make an independent determine as to whether the product is safe, only that it is comparatively as safe as another product already on the market. This is precisely why the process is irrelevant here.[3]

Furthermore, Bard relies almost exclusively on case law which does not involve and had nothing to do with 510(k) cleared products. The only[4] potentially relevant case Bard cites involving a 510(k) cleared product, *Winebarger v. Boston Scientific Corp*., is a revisitation of a prior MDL ruling excluding 510(k) clearance evidence. The *Winebarger* matter was part of MDL 2326 where the *Cisson* line[5] of rulings excluding 510(k) clearance

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[2] Bard's own submitted documents state that the FDA communicated, "You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish **substantial equivalence**. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations." *Id.* (emphasis added).

[3] As the Fourth Circuit recognized prior to its *Cisson* decision in *Almy v. Sebelius*, 679 F.3d 297 (4th Cir.2012), "'[A] section 510(k) notice **generally does not involve clinical data showing safety and effectiveness**.' 54 Fed. Reg. 4307. Section 510(k) approval requires only that a device be 'substantially equivalent' to another device that the FDA has already approved for marketing, and **not that the device have been clinically examined for safety and effectiveness**. The Supreme Court has emphasized this distinction, noting that a device approved under 510(k) '**has never been formally reviewed ... for safety or efficacy**.'" *Id*. at 308 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis added)).

[4] Bard cites to this Court's opinion in *Placencia v. I-Flow Corp.*, 2012 WL 5877624 (D. Ariz. Nov. 20, 2012) as if it made an evidentiary ruling on the admissibility of 510(k) clearance evidence, yet Plaintiff's understanding of that opinion is that it was the Court's ruling on a motion for summary judgment and admissibility of such evidence was not yet before the Court. *See* Def. Resp. Mot., at 4, fn. 5.

[5] The "*Cisson* line" of rulings excluding 510(k) clearance evidence and lack of enforcement by the FDA are cited in Footnote 2 of Plaintiff's Memorandum of Law in Support of Plaintiff's Motion in Limine to Exclude Reference to FDA 510(k) Clearance and Lack of FDA Enforcement. (Doc. 9529).

evidence and lack of enforcement emanated and were upheld by the Fourth Circuit. However, *Winebarger* was remanded back to its transferor court after the MDL's decision; the District Court of the Western District of North Carolina. 2015 WL 5567578 (W.D.N.C. Sep. 21, 2015). There, the district court reconsidered the plaintiff's motion *in limine* to exclude FDA-related evidence and, based on what it described as the broad language of the North Carolina Product Liability Statute, deemed FDA clearance evidence was a criterion to be considered, *i.e.*, the transferor court didn't find it to be a "standard" but deemed it a "criterion" to be considered under North Carolina law. 2015 WL 5567578 at *4-5. But due to the "risk of misleading and confusing the jury", the court's recognition that "[a] mini-trial[6] on the FDA 510(k) clearance process would be a waste of time," and finding that there was "a legitimate concern that jurors might place too much emphasis on the 510(k) clearance" process, the district court ruled that 510(k) clearance evidence could **only** be admissible if specific limiting instructions addressed these concerns. *Id*. at 7. Thus the one relevant case Bard relies on recognized the problems of time wasting, jury confusion, risk of a mini-trial, and the potential unwarranted gravitas a jury may assign to the clearance process. These problems will inevitably arise should such questionable evidence be presented in a trial where strict time limits have been imposed and advance rulings have already been made to keep out evidence of questionable probative value.

Plaintiff's position, on the other hand, is legally sound and supported by multiple well-reasoned decisions in addition to the *Cisson* line of cases excluding FDA evidence where any minimal probative value is substantially outweighed by the significant risk of prejudice that jurors will accord some credibility to a government agency that will not appear in the trial or be subject to cross-examination.

[6] Plaintiff presented evidence in her brief that could potentially be excluded to include the FDA Warning Letter, certain regulatory expert testimony, and testimony of Bard witnesses (e.g., Mary Edwards as far as clearance testimony; some witnesses such as Ms. Edwards offer non-clearance related testimony that would still be relevant).

B. Lack of FDA Enforcement Action Is Irrelevant and Immaterial.

Evidence of lack of FDA enforcement action against Bard would mislead a jury into drawing conclusions and making up its own inferences about something that didn't happen. Therefore it should be excluded as prejudicial, confusing, and misleading. Fed. R. Evid. 402, 403. Whether the G2 filter was on the market for two years prior to Ms. Booker receiving it is irrelevant. Fed R. Evid. 401. Inviting speculation as to why the G2 filter was not subject to either FDA action or inaction is impermissible. FDA's motive, intent, or state of mind is inadmissible because it is unknowable since FDA was never a party to these actions. *See, e.g., In re Fosamax Prod. Liab., Litig*., 645 F. Supp. 2d 164, 192 (S.D.N.Y 2009). Also, Bard cannot suggest to the jury that it draw inferences regarding FDA's "broad authority" to regulate medical devices. Def. Resp. Mot., at 8. Moreover, the Supreme Court acknowledged in *Lohr* that "FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs since … the authority is **rarely invoked, if at all**." *Medtronic v. Lohr*, 518, U.S. 470, 487, n.7 (1996) (emphasis added).

C. Conclusion

Accordingly, Plaintiff respectfully requests that this Court enter an Order (1) granting this motion; (2) prohibiting at trial all evidence and argument relating to the 510(k) clearance process and regulatory scheme; and (3) prohibiting at trial all evidence and argument regarding the FDA's lack of enforcement action as to Bard's IVC filters.

RESPECTFULLY SUBMITTED this 25th day of January, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of January 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti